California Board of Pharmacy
State of Pedigree and EPC/RFID Standards

December 12, 2006

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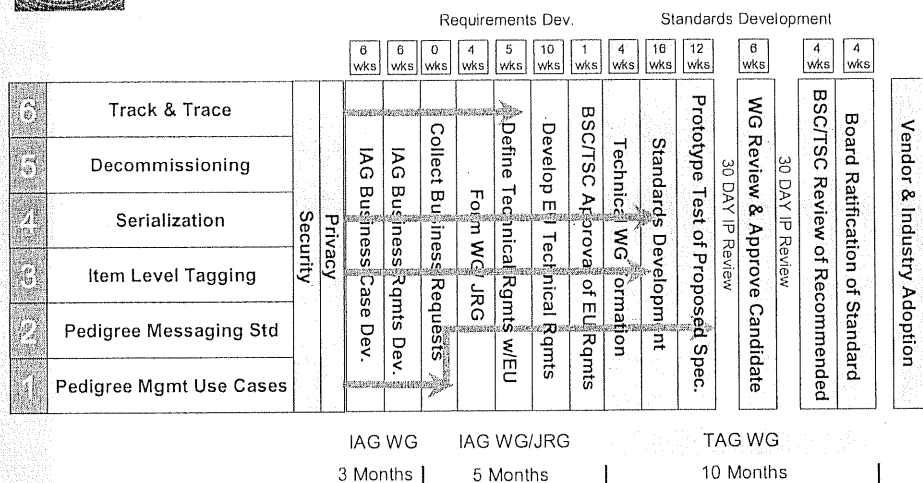

Agenda

- Standards Progress

- Pedigree Review Event

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Standards Update
Last Report

Requirements Dev.   Standards Development

| 6 wks | 6 wks | 0 wks | 4 wks | 5 wks | 10 wks | 1 wks | 4 wks | 16 wks | 12 wks | | 6 wks | | 4 wks | 4 wks |

| Track & Trace |
| Decommissioning |
| Serialization |
| Item Level Tagging |
| Pedigree Messaging Std |
| Pedigree Mgmt Use Cases |

Privacy / Security

IAG Business Case Dev.
IAG Business Rqmts Dev.
Collect Business Requests
Form WG / JRG
Define Technical Rqmts w/EU
Develop EU Technical Rqmts
BSC/TSC Approval of EU Rqmts
Technical WG formation
Standards Development
Prototype Test of Proposed Spec.
30 DAY IP Review
WG Review & Approve Candidate
30 DAY IP Review
BSC/TSC Review of Recommended
Board Ratification of Standard
Vendor & Industry Adoption

IAG WG   IAG WG/JRG   TAG WG
3 Months | 5 Months | 10 Months |

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As of 9/26/2006
As of 12/12/2006

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Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define all supply chain use cases, processes and information needs for use in creating a Pedigree Messaging Standard.

Status: Complete

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Standards Update

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

6	Track & Trace
5	Decommissioning
4	Serialization
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2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

- All Standards work complete (Certification Requirements due 12/20/2006).
- Prototype event was successful.
- Passed Technical Review
- Intellectual Property Review period started
- **Ratification of standard anticipated 4Q/2006.**

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Standards Update

6	Track & Trace
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Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.

- HF Standard expected 3Q07.
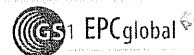
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Standards Update

6	Track & Trace
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Define requirements the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.

- Joint group formed between EPCglobal Healthcare and Life Sciences Business Action Group (HLS) and GS1 Healthcare User Group (HUG).

- All remaining issues to be addressed by new Serialization group.

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Standards Update

6	Track & Trace
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Define requirements and/or guidelines for decommissioning tags as they leave the supply chain.

Status:

- HLS Work Group to be chartered & initiated January 2007
- Anticipate six month effort
- DEA interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

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Standards Update

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

6	Track & Trace
5	Decommissioning
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1	Pedigree Mgmt Use Cases

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges have been completed
- Common vocabularies and location identifiers have been drafted
- Additional use cases to be addressed include:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
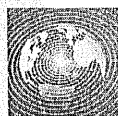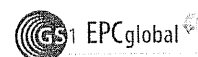- Data Sharing Strategy & Guidelines are currently being addressed

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Pedigree Messaging Standard

Expected Ratification by end of 2006

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Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes

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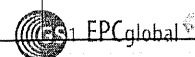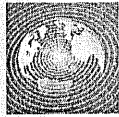
Next Steps

- Walk Board of Pharmacy through Pedigree scenarios

- Host workshop for Regulators from States with electronic pedigree bills

- Industry Adoption WG formed
  - Working with Industry Associations on Serialization & Item Level Tagging issues

- Upcoming events:
  - EPCglobal Inc Joint Action Group Event (Jan 8-12, 2007)
  - Ongoing work on
    - Serialization
    - Item Level Tagging
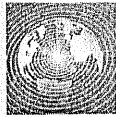   - Track and Trace

- Provide regular status updates to CA BoP

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Pedigree Review Event
Agenda

- Structure of the Pedigree Standard

- Implementation Guidelines Review

- Walkthrough seven Pedigree scenarios

- Pedigree Software Certification Process

- Pedigree Standard Revision Process

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Planned Activities
Regional Hospital Summits

Date	City	Event
January 23rd	Dallas	
February 20th	California	
March 1st	New Orleans	Healthcare Information and Management Systems Society (HIMSS)
March 13th	Boston	
April 17th	Chicago	
May 10th	Washington D.C.	American Hospital Association (AHA)

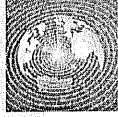GS1 EPCglobal

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Questions?

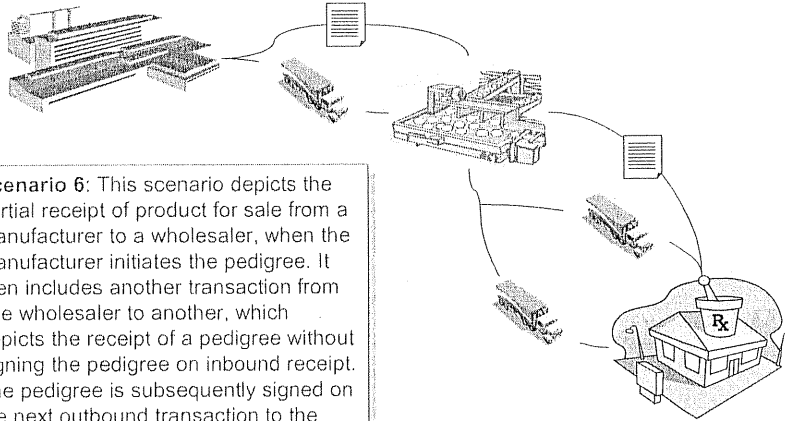GS1 EPCglobal

Additional Slides
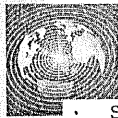
EPCglobal Pedigree Prototype Event
Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.

- **Scenario 2:** This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

- **Scenario 3:** This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products ·

- **Scenario 5:** This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.

- **Scenario 6:** This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

- **Scenario 7:** This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

EPCglobal Pedigree Prototype Event
Sample Scenario

Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

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